Prospective evaluation of the correlation between torso height and aortic anatomy in respect of a fluoroscopy free aortic balloon occlusion system

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Background. *To report the lengths of key torso vascular and to develop regression models that will predict these lengths, based on an external measure of torso height (EMTH, sternum to pubis) in the development of a fluoroscopy free balloon occlusion system for hemorrhage control.*
Methods. *We conducted a prospective, observational study at a Combat Support Hospital in Southern Afghanistan using adult male patients undergoing computed tomography (CT). EMTH was recorded using a tape measure and intra arterial distance was derived from CT imaging. Regression models to predict distance from the common femoral artery (CFA) into the middle of aortic zone I (left subclavian artery to celiac trunk) and zone III (infrarenal aorta) were developed from a random 20% of the cohort and validated by the remaining 80%.*
Results. *Overall, 177 male patients were included with a median (interquartile range [IQR]) age of 23 (8) years. The median (IQR) lengths of aortic zone I and III were 222 (24), 31 (9), and 92 (15) mm. The mid zone distance from the left and right CFA to zone I were 423 (27) and 418 (29) and for zone III 232 (21) and 228 (22). Linear regression models demonstrated an accuracy between 99.3% to 100% at predicting the insertion distance required to place a catheter within the middle of each aortic zone.*
Conclusion. *This study demonstrates the use of morphometric analysis in the development of a fluoroscopy free balloon occlusion system for torso hemorrhage control. Further study in a larger population of mixed gender is required to further validate insertion models. (Surgery 2014;155:1044 51.)*

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Hemorrhage is the leading cause of potentially preventable death in military trauma.[1-3] The majority of hemorrhagic foci originate in noncompressible regions, such as the torso and junctional zones (groin and axilla), accounting for 86.5% of hemorrhage-related combat deaths.[4] Furthermore, almost 9 out of 10 deaths occur in the prehospital setting.[4] Current management relies on operative hemorrhage control, which is contingent on patients surviving to hospital admission.[5] Even then, many patients arrive in extremis, with circulatory collapse, where reactive maneuvers such as resuscitative thoracotomy and aortic cross-clamping yield few survivors.[6]

Resuscitative endovascular balloon occlusion of the aorta (REBOA) provides inflow control and afterload support to patients with circulatory collapse from hemorrhage.[7] It can either be inserted prophylactically in patients at risk of hemorrhage and then inflated in the event of a

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deterioration, or as a substitute to open cross-clamping in the moribund patient.[8] REBOA is designed as a proactive maneuver, which can be inserted in austere circumstances, providing a physiologic bridge to definitive hemorrhage control.

The clinical use of this technique was first described in the 1950s,[9] with further reports in the 1980s.[10,11] Despite some favorable outcomes, technological limitations relating to arterial access, balloon construction, and placement mean that its adoption was not widespread. However, following the evolution of endovascular surgery and the experience with aortic balloon occlusion during endovascular aneurysm repair,[12,13] many of these constrains have been overcome. The use of REBOA in traumatic hemorrhagic shock is currently being revisited clinically using "off-the-shelf" devices,[14] but there is also active research into trauma-specific catheters.[15]

To facilitate REBOA deployment, the aorta has been characterized into 3 functional zones: Zone I extends from the origin of the left subclavian to the celiac trunk, zone II is from the celiac trunk to the lowest renal artery, and the infrarenal aorta constitutes zone III (Fig 1).[7] Zones I and III serve as "landing zones" for occlusion in specific injury patterns. Zone I occlusion provides resuscitation in circulatory arrest and control for abdominal exsanguination and zone III occlusion is for ileofemoral junctional hemorrhage.[5]

Current technology requires fluoroscopy for precision placement, which limits the deployment of REBOA systems in the prehospital or emergency department setting. Unassisted blind insertion is fraught with potential complications, varying from aortic arch placement precipitating cerebral ischemia to iliac artery occlusion inadequately controlling inflow.

A potential solution to aid fluoroscopy-free placement is to use an external anatomic measure to predict internal vascular length. A linear relationship has been previously demonstrated between aortic length and torso height.[16] The aim of this study was to develop predictive models of REBOA insertion distance, based upon an external measure of torso height (EMTH) correlated with internal vascular distance, the accuracy of which will be then assessed using prospective EMTH data, collected in a realistic clinical setting.

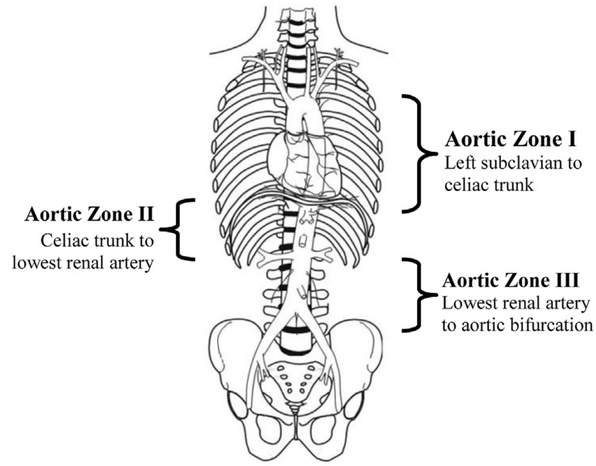

Fig 1. The three aortic zones. (Reproduced from Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. J Trauma 2011; 71:1869 72, with kind permission from Wolters Kluwer Health).

METHODS

This prospective, observational study was performed after approval from the UK Royal Centre for Defence Medicine Academic Unit and the US Medical Research and Material Command. The study was conducted at the Combat Support Hospital in Camp Bastion, Helmand Province, Southern Afghanistan. This hospital is unique in the theater of Afghanistan as it is a joint UK–US facility, staffed by clinicians from each nations military among others. It is also the busiest coalition medical facility in the region, providing comprehensive trauma care for both military and civilian patients.[17] The infrastructure includes two 64-slice computed tomography (CT) scanners, in addition to an emergency department, operating suite and critical care facilities.[18] Data was collected over 2 time periods (July 2011–September 2011 and November 2011–January 2012), during the deployments of 2 authors (AS and JJM).

Study population. A convenience sample of male patients aged between 18 and 50 years, who underwent contrast-enhanced CT imaging of the chest, abdomen, and pelvis as part of their care, were included in the study. A convenience sample was used, rather than consecutive patients, because of the brisk operational tempo and single-handed nature of the data collection. Nation status was dichotomized into patients of Afghan origin (military or civilian) and were termed "Host National" and the remaining were termed "Coalition Military." Enemy combatants were not included in the study.

Once a patient had been identified as requiring CT imaging, an EMTH was recorded before discharge. This was performed using a tape measure, held parallel to the subjects craniocaudal axis, to obtain the distance from the jugular notch

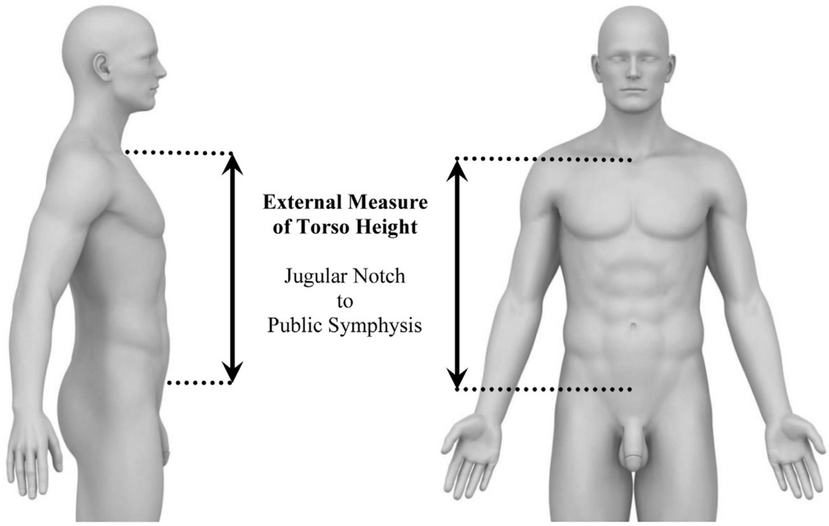

Fig 2. Landmarks demonstrating the external measure of torso height. (Images reproduced under license courtesy of Peter Lecko/123rf.com.)

to the pubic symphysis (Fig 2). All tape measurements were performed by 1 of 2 individuals (AS or JJM) to the nearest centimeter.

Using a CT workstation, the centerline distances from the left and right femoral artery (CFA), at the level of the mid-point of the femoral head, to several key aortic landmarks (bifurcation, take off of the lowest renal artery, celiac and left subclavian) were calculated. This technique takes into account vessel tortuosity and angulation, providing for precision measurements. The CFA landmark was chosen as a possible site of arterial access for the insertion of a REBOA system. The EMTH was also repeated using the CT calipers on the sagittal view of the scout film. All CT measurements were to the nearest millimeter.

Statistical analysis. Initially, the measurements of key vascular landmarks and torso height by CT and tape measure were reported for the entire cohort. Specifically, the distance from the left and right CFA insertion points to the mid-points of zones I and III were calculated. These distances represent the insertion length required for a REBOA system to occlude the aorta at the mid-point or "landing zone" of each respective zone.

After this, a 20% sample of the study group was selected at random and used as a development cohort to generate linear regression models of insertion using the CT EMTH as the dependent variable. Model group 1 included both insertion length and nation status (Host National or Coalition Military) as covariates, whereas model group 2 only utilized insertion length. Models were generated for insertions through both left and right CFAs and for the mid-points of zones I and III, 4 in total. The strength of each regression model was presented using the coefficient of determination adjusted for sample size (adjusted R^2). Analysis of variance was used to test the null hypothesis. Model group 3 consisted of a constant which was the median insertion distance for the population, without adjustment for any parameter.

After the development of the insertion models, the remaining 80% of the study group was used as a validation cohort. The tape EMTH was used in conjunction with the model equations to generate predicted insertion lengths. These predicted lengths were then correlated with the observed lengths and the strength of the linear dependence reported using Pearson's correlation coefficient. Accuracy was also assessed by the proportion of subjects "landing" both within the zone and within the middle 60% of the zone. The latter was chosen, because this leaves a 20% safety margin at either end of the zone to accommodate a theoretical balloon "foot-print." Box-and-whisker plots were used to graphically demonstrate the accuracy of the models within the proximal and distal extent of the aortic zones, expressed as a proportion.

Data were recorded and organized in an Excel spreadsheet (Microsoft, Redmond, WA) and then imported into SPSS version 20 (IBM, New York, NY), which was used to perform the statistical analysis. Data which was not normally distributed was presented as medians, with 25th and 75th quartiles, as well as minimum and maximum values.

RESULTS

Data were collected on 80 and 97 patients during the 2 time periods, providing a total cohort for analysis

Table I. Measurements of key vascular landmarks (n = 177)

Distance (mm)	*Minimum*	*25th Percentile*	*Median*	*75th Percentile*	*Maximum*
Vessel lengths					
Left CFA to AB	116	174	182	194	223
Right CFA to AB	121	178	187	199	242
Left CFA to lowest RA	179	264	275	287	312
Left CFA to CA	198	296	307	319	357
Left CFA to left SCA	348	514	530	548	590
Zone lengths					
Zone I	141	209	222	233	255
Zone II	16	27	31	36	70
Zone III	63	84	92	99	123
Insertion lengths					
Right CFA mid zone I	280	409	423	436	488
Left CFA mid zone I	277	404	418	433	468
Right CFA mid zone III	152	223	232	244	286
Left CFA mid zone III	148	218	228	240	268
Torso height					
Measured by CT	366	517	533	552	590
Measured by tape	370	530	540	560	610

AB, Aortic bifurcation; *aortic zone I*, left subclavian to celiac trunk; *aortic zone II*, celiac trunk to lowest renal artery; *aortic zone III*, lowest renal artery to aortic bifurcation; *CFA*, common femoral artery; *CT*, computed tomography; *RA*, renal artery; *SCA*, subclavian artery.

of 177 patients. The median age of the cohort was 23 (interquartile range [IQR], 8) with 104 (58.8%) of Host National origin. There were no missing data.

Table I provides a summary of the measurements of key vascular landmarks for the total cohort, measured in millimeters. The median distance from the right CFA to the aortic bifurcation was longer than from the left CFA by a distance of 5 mm. Zone I was the longest of the aortic zones with a median measurement of 222 (IQR, 24), followed by zone III with 92 (IQR, 15). Zone II was the shortest zone, with an median distance of 31 (IQR, 9).

Correspondingly, the insertion length from the CFA to the mid-point of each zone was longer from the right side compared with the left. For occlusion of the mid-point of zone I, the median insertion from the right CFA was 423 (IQR, 27) and from the left CFA was 418 (IQR, 29). For zone III occlusion, the insertion distance was considerably shorter than zone I, with a median distance from the right of 232 (IQR, 21) and from the left of 228 (IQR, 22). The EMTH by CT and tape measure were in similar agreement with respective values of 533 (IQR, 34) and 540 (IQR, 30).

A 20% model development cohort (n = 36) was selected at random and compared with the remaining 80% model validation cohort (n = 141) for key measurements. There was no difference in EMTH values and respective insertion lengths ($P > .01$) between the groups using a Mann–Whitney rank-sum test.

Linear regression was used to develop several models to predict insertion length (Table II). Model group 1 used the CT EMTH as the dependent variable and the zone insertion length and nation status as the independent variables. The models generated for zone I occlusion had adjusted coefficient of determination values of 0.803 and 0.824 for left and right insertions, respectively. Zone III demonstrated a lower coefficient of determination with values of 0.613 and 0.642, respectively.

Model group 2 utilized the CT EMTH as the dependent variable and zone insertion length as the independent variable. The models in group 2 performed similarly to group 1, with the strongest models observed in zone 1 with adjusted correlation of determination values of 0.803 and 0.824 for right and left insertion, respectively. Zone III models for the right and left insertion scored 0.620 and 0.642, respectively. No correlation was determined for model group 3 because the insertion distance was a constant: 418 for zone I and 229 for zone III.

The tape EMTH from the validation cohort (n = 141) was used in conjunction with the 3 model groups to calculate predicted insertion distances (Table III). Model group 1 demonstrated a good correlation for the zone I insertion with a Pearson's correlation of 0.740 for each side. This was reflected by 100% of predicted insertion lengths landing within zone 1 and almost 100% of patients within the middle 60% of the zone (Table III;

Table II. Linear regression models, developed with and without regard to nation status, from 20% (n = 36) of the overall cohort

Model group	*Equation*	*Adjusted coefficient of determination*	P *value*
1*			
R CFA to mid zone I	$E(Y) = \beta_0 + \beta_1 X_1 + \beta_2 X_2$	0.803	<.001
L CFA to mid zone I		0.824	<.001
R CFA to mid zone III		0.613	<.001
L CFA to mid zone III		0.642	<.001
2†			
R CFA to mid zone I	$E(Y) = \beta_0 + \beta_1 X_1$	0.806	<.001
L CFA to mid zone I		0.828	<.001
R CFA to mid zone III		0.620	<.001
L CFA to mid zone III		0.642	<.001
3‡			
Any CFA to mid zone I	$E(Y)$ = median (insertion length)	n/a	n/a
Any CFA to mid zone III		n/a	n/a

*Model group 1 incorporates nation status as a covariate.
†Model group 2 developed with no regard to nation status.
‡Model group 3 inserts to the median population zone insertion length.
AB, Aortic bifurcation; *aortic zone I*, left subclavian to celiac trunk; *aortic zone II*, celiac trunk to lowest renal artery; *aortic zone III*, lowest renal artery to aortic bifurcation; *CFA*, common femoral artery; *CT*, computed tomography; $E(Y)$, predicted insertion length; *n/a*, not applicable; *RA*, renal artery; *SCA*, subclavian artery; X_1, torso height; X_2, nation status.

Table III. Predicted versus observed values, correlation and accuracy of placement (within zone boundaries) from the remaining 80% (n = 141) of the cohort

Distance (mm)	*Observed length Median (95% CI)*	*Predicted length Median (95% CI)*	*Correlation* Pearson's	*Correlation* P *value*	*Accuracy* Total zone, n (%)	*Accuracy* Middle 60% of zone, n (%)
Model group 1						
R CFA to mid zone I	423 (418 427)	432 (429 435)	0.740	<.001	141 (100)	140 (99.3)
L CFA to mid zone I	419 (414 422)	427 (424 431)	0.740	<.001	141 (100)	141 (100)
R CFA to mid zone III	232 (231 236)	241 (238 242)	0.504	<.001	141 (100)	126 (89.4)
L CFA to mid zone III	228 (226 232)	238 (234 238)	0.491	<.001	140 (99.3)	127 (90.0)
Model group 2						
R CFA to mid zone I	423 (418 427)	431 (429 436)	0.741	<.001	141 (100)	140 (99.3)
L CFA to mid zone I	419 (414 422)	426 (425 431)	0.741	<.001	141 (100)	140 (99.3)
R CFA to mid zone III	232 (231 236)	238 (238 241)	0.523	<.001	141 (100)	128 (90.8)
L CFA to mid zone III	228 (226 232)	234 (233 237)	0.517	<.001	141 (100)	131 (92.9)
Model group 3						
R CFA to mid zone I	423 (418 427)	418 (n/a)	(n/a)	(n/a)	140 (99.3)	138 (97.9)
L CFA to mid zone I	419 (414 422)	418 (n/a)	(n/a)	(n/a)	139 (98.6)	138 (97.9)
R CFA to mid zone III	232 (231 236)	229 (n/a)	(n/a)	(n/a)	138 (97.9)	127 (90.0)
L CFA to mid zone III	228 (226 232)	229 (n/a)	(n/a)	(n/a)	138 (97.9)	129 (91.5)

CFA, Common femoral artery; *aortic zone I*, left subclavian to celiac trunk; *aortic zone III*, lowest renal artery to aortic bifurcation.

Fig 3). For zone III insertion, Pearson's correlation fell to 0.504 and 0.491 for right and left insertion, respectively, although all but 1 patient landed within the desired zone. When assessing accuracy to within the middle 60% of zone III, the left and right insertion were 89.4% and 90.0% accurate respectively (Table III; Fig 4).

A similar pattern was observed for model group 2, albeit with a slightly higher Pearson's value across all zones (Table III). Zone I scored 0.741 for both insertion sides, with a 100% and 99.3% accuracy for total zone and middle 60% zone accuracy, respectively (Fig 3). Zone III achieved correlations of 0.523 and 0.517 for the right and left insertion, respectively. This translated to 100% of patients landing within the zone and 90.8% and 92.9% of the right and left insertions landing within the middle 60% of the zone (Fig 4).

Pearson's correlations could not be generated for model group 3 because this used a fixed

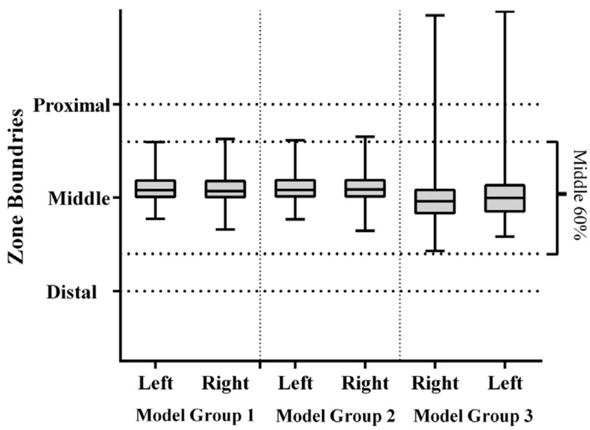

Fig 3. Box and whisker plot of the median, interquartile, and maximum and minimum range of predicted place ment within zone I, as a proportion of zone extent.

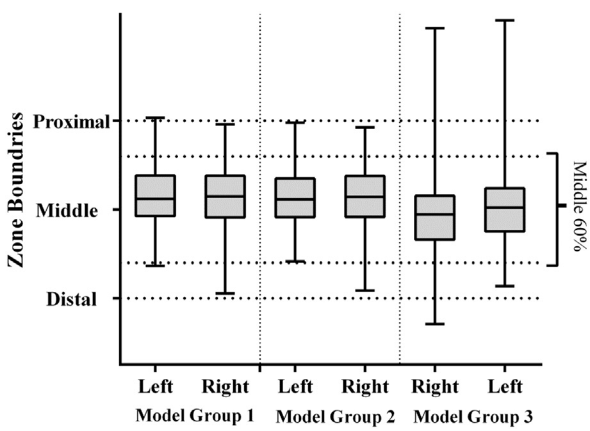

Fig 4. Box and whisker plot of the median, interquartile, and maximum and minimum range of predicted place ment within zone III, as a proportion of zone extent.

insertion distance (Table III). The majority of patients were landed within their desired zone: 99% for zone I and 98% for zone III. When assess the proportion of patients landing within the middle 60% of the zone, 97.9% accuracy was achieved for zone I, and >90% for zone III (Figs 3 and 4).

DISCUSSION

The current study represents the first prospective evaluation of aortic morphometry in the development of a fluoroscopy free REBOA system for use in noncompressible hemorrhage. A strong correlation exists between torso height and torso arterial morphometry. This is important, because torso height can be easily measured in the emergent setting and used to reliably predict the insertion length required for occlusion of aortic zones I and III by a REBOA system. A reliable and reproducible method to predict insertion length is essential to avoid incorrect placement, which could have potentially lethal consequences.

This study is an extension of our groups' previous morphometric analyses characterizing the external–internal relationship between torso extent and aortic length. Stannard et al[16] retrospectively analyzed a CT data repository of 200 scans to identify a cohort of 88 that were suitable for inclusion. That study also examined a male-only population and their reported median zones lengths are in agreement with the current study. Those investigators correlated descending aortic length with torso height (sternum to pubis) and described a correlation of determination of 0.454. Importantly, the current study represents a progression of Stannard et al's work[16] by using a more robust prospective methodology. The acquisition of more datapoints and subjects has enabled the analysis of ethnicity and a more detailed mathematic exploration of the relationship between torso height and vascular length.

Accurate placement is essential to avoid complications; occlusion proximal to zone 1 could cover the origin of 1 or both carotid arteries, theoretically precipitate an ischemic stroke, and dangerously elevate cardiac afterload. Inadvertent zone II placement and occlusion of the celiac trunk or mesenteric arteries could induce visceral ischemia, adding to the patients metabolic burden. The concern with placement in an iliac artery is that contralateral inflow control is not established, which could be driving pelvic or junctional hemorrhage.

The current study yields some interesting results that are important to discuss. The finding that the inclusion of nation status as a covariate adds little to the accuracy of the models is at first surprising. However, military personnel are drawn from numerous ethnic backgrounds—Caucasian, Hispanic, African American, Samoan, and Nepalese to name but a few. This means that the binary categorization of nation status is likely an oversimplification of a complex issue. To understand the impact of ethnicity on aortic morphometry, a much larger population with more detailed ethnic origin data is required.

The current study reports 3 insertion models, 2 of which were derived from linear regression and third used the median population measurement as an insertion length. Interestingly, the use of population medians (model group 3) performed almost as well as either of the regression models. This result may lead to the suggestion that the use

of regression modeling is overly complicated and therefore redundant. However, although the cohorts ethnicity may be fairly heterogeneous, their torso dimensions are relatively homogenous. For example, the IQR for torso height and zones I and III are only 35, 24, and 15 mm respectively. This, combined with the relatively large lengths of the zones, means that insertion to the population median, without adjustment, will have a significant chance of accurate placement.

However, the regression models are essential for guiding the placement of patients who lie outside population norms. This is best demonstrated by examining the whisker range plots in Figs 3 and 4. Although the majority of patients in model group 3 are within the zone boundaries, the range extends significantly beyond the proximal and, in some cases, the distal extent of the zone. After the use of regression in model groups 1 and 2, essentially all are within the zone boundary.

Furthermore, it is important to acknowledge that the blind deployment of a REBOA system requires more than just an insertion equation; the catheter is required to remain with the aorta and be resistant to deviation down side branches. This challenge is being met with novel catheter designs that incorporate a low-profile construction with novel self-centering technology to ensure minimal deviation out with the aorta during insertion.[15]

The current study has a number of limitations that are important to understand. The reported dataset is limited and does not include other important factors that may affect torso measurements and arterial lengths, such as body habitus, gender, and age. A greater number of subjects with a greater number of variables would allow for better modeling and more rigorous evaluation of predicted insertion lengths. Importantly, future populations must also be relatively heterogeneous to better understand the impact of variation. For example, the tortuosity of vasculature increases with age,[19,20] something vital to understand for the successful deployment of REBOA systems in older patients.

These limitations have largely come about owing to the circumstances of the current studies data collection. Data was collected by 2 military surgeons, deployed in an operational Combat Support Hospital; therefore, the data parameters collected were minimal. Furthermore, because of the nature of combat operations, the study population was male, with a bias toward patients in their 20s and 30s of life.

Despite these limitations, this prospective, observational study demonstrates the feasibility of this methodology in the development of a fluoroscopy free REBOA system. The relatively large size of zones I and III lend themselves, as well as functional zones of occlusion. The use of linear regression modeling has led to almost 100% accurate prediction of insertion distances. The influence of ethnicity on aortic morphometry requires further study along with additional variables such as age, body habitus, and gender.

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